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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,763	02/14/2001	Norbert Windhab	260/095	2275

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 06/25/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/783,763

Applicant(s)

WINDHAB ET AL.

Examiner

T. D. Wessendorf

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**– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-112 is/are pending in the application.
- 4a) Of the above claim(s) 1-95,97,100-102 and 108-110 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 96,98,99,103-107,111 and 112 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group IV, claims 96-112, species Ig and fragments; p-RNA; covalent for the binding immunoreaction components and non-covalent (biotin/streptavidin) for complementary pairing component member in Paper No. 7 is acknowledged.

Claims 1-95, 97, 100-102 and 108-110 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

Status of Claims

Claims 1-112 are pending in the application.

Claims 1-95, 97, 100-102 and 108-110 are withdrawn from consideration, as stated above.

Claims 96, 98-99, 103-107 and 111-112 are under examination.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (typographical, grammatical and/or idiomatic). Applicant's

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cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: composition of matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 96, 98-99, 103-107 and 111-112 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a p-RNA as the pairing component; an microelectronic array and Ig, does not reasonably provide enablement for the broadly recited pairing complexes, array and Ig derivatives or fragments. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The scope of enablement provided in the specification is not commensurate in scope with the broadly recited composition

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of matter having undefined components. The disclosure merely describes a pairing complex containing p-RNA. There is no indication in the specification that the embodied species described therein would reasonably be predictive or applicable to any kind of molecular species and molecular pairing system. It would take an undue amount of experimentation for one skilled in the art to determine even a single parameter of the broadly claimed composition. The factors that are to be considered in the determination of undue experimentation are disclosed in *In re Wands*, (U.S.P.Q. 2d 1400 (CAFC 1988)). These include: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the art, the predictability of the art and the breadth of the claims.

1). The specification fails to give adequate direction and guidance in how to readily go about determining the different kind(s) of pairing complexes or derivatives of Ig or fragments and the array cover by the broad claimed composition of matter.

2). Applicants have failed to provide any working examples for any immunoreaction-pairing complexes. The only working example describe in the specification is drawn to a composition comprising p-RNA as the pairing complex. See page 28, lines 7-20 as to the drawback in using e.g., DNA and RNA because of cross-hybridization and assay problem.

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3). The state of the prior art is such that techniques of pairing complex formation containing any type of components and its use has not yet advanced that one can make a priori statement based on a single species and its applicability to any pairing complex of unknown constitution.

4). The art is inherently unpredictable that even a single factor, as temperature (minus the other environmental factors) could result in the production of a complex where the desired immunoreaction-pairing complex is compromised. See further the Gallop et al reference (Jrnl. of Medicinal Chemistry) e.g., at page 1235, col. 2 and page 1247, col. 1. Thus, at the time of applicants' invention few generalizations have been made in this field since not only the conformational but also the topological, the spatial arrangement of the amino acids relative to each other have to be considered in the making of even a single pairing complexes as p-RNA comprised in the instant composition.

5). The breadth of the claims encompasses a large combinations for the different recited variables such as the large diversity of monomers, Ig derivatives and fragments and pairing complex in the making of a composition and the assay test necessary to determine the effect, if any, of said composition. The nature of the invention is such that the use of diverse pairing complex of undefined constitution is still consider undeveloped, at the time of applicants' invention.

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6). Therefore, while the level of skill in the art is high, the peptide and/or DNA technology is so unpredictable that it would require undue experimentation to make the invention commensurate in scope with that claimed in the absence of guidance or direction as set forth above.

35 USC 112, first paragraph requires that the scope of the claims bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art such that the invention can be practiced without undue experimentation. In an unpredictable art, such as peptide reactions or chemistry, guidance is needed since the scope of enablement varies inversely with the degree of unpredictability of the factors involved. A person skilled in the art would not be able to predict without difficulty whether the performance characteristics of the broad claimed substance library is predictable from the single embodied pairing complex, p-RNA. [It is suggested applicants limit the claims to the species, as elected].

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35

U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 96, 98-99, 103-107 and 111-112 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 96 is indefinite in the recited set of **binding** immunoreaction component-pairing component complexes. It is not clear as to whether the binding refers to the complexes formed or ability to bind to one or more analyte. The term "binding" is a method step limitation, not a composition. The use of parenthesis is confusing as to whether the compounds recited therein form a part of the claim or not. It is further unclear as to what the letters in the parenthesis stand for. It is suggested that applicants positively recite what the different letters stand for. The metes and bounds of the "more" than one analytes is not clearly set forth in the claims or specification. Also, it is not clear as to the number of components present in a set, in the context of the claim.

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B. Claim 98 is indefinite as to the term "moiety" This seem to go against the conventional usage of said term i.e., as a part of a compound and not the compound itself e.g., Ig.

C. "The complementary" in claim 107 lacks antecedent basis of support from the base claim. This claim is a duplicate of claim 99 since the same limitation is being claimed.

D. In claim 111, "at least" one labeled analyte standard" does not further limit the base claim. The base claim does not recite for an analyte standard.

E. Claim 112 does not further limit the base claim and broadens the base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly

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or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 96, 98, 103-106 and 111-112 are rejected under 35 U.S.C. 102(e) as being anticipated by Cubicciotti (U.S. 6,287,765).

Cubicciotti discloses at page 16, line 40 up to col. 22, line 67 a composition comprising of a "bispecific nucleic acid antibody" meaning a bivalent or multivalent aptameric device, synthetic heteropolymer or multimolecular device which is capable of specifically recognizing at least two different target molecules. The term "bivalent," when used in reference to nucleotide-based, aptameric and heteropolymeric discrete structures and nonnucleotide multimolecular structures, templates, scaffolds and molecules, means comprising at least two recognition sites. Different specific binding pairs" means two specific binding pairs whose four members comprise at least three different chemical identities. Exemplary pairs of different specific binding pairs include, but are not limited to; two antigen/antibody pairs with different specificities (e.g., peroxidase/anti-peroxidase and fluorescein/anti-fluorescein); Even biotin/streptavidin and biotin/avidin are

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different specific binding pairs, because the two specific binding pairs comprise three distinguishable chemical identities (i.e., biotin, streptavidin and avidin). See specifically Example 16, col. 224. Accordingly, the specific composition of Cubicciotti which recites an antibody with a nucleotide-pairing complex attached to a solid phase nucleotide fully meets the broad claimed composition.

Allowable Subject Matter

Claims 99 and 107 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and overcoming the 112 rejections.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Guire et al discloses a replicable probe array.

A copy of the Cubicciotti reference is included in the copending application, S.N. 09374,338. The Gallop reference was provided in the 09/180,651 application.

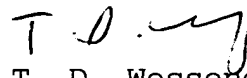
Any inquiry concerning this communication or earlier communications from the examiner should be directed to **T. D.**

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Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
June 16, 2003